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09/918,063	07/30/2001	Eric R. Weber	DI-12	2551

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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	8

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,063	WEBER ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 24-27* is/are pending in the application.

4a) Of the above claim(s) *7-9,13-15 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-12 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on December 2, 2002 has been entered as Paper No: 8. Since newly submitted claim 27 is directed to a method to produce a protein and is drawn to the nonelected invention in Group II (see Paper No. 5), claim 27 is considered to be directed to an invention that is independent or distinct from the invention originally claimed. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The claims pending in this application are claims 1-15 and 24-27 with claims 7-9, 13-15, and 27 withdrawn from consideration as the result of the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on December 2, 2002.

Claim Objections

2. Claim 24 is objected to because of the following informality: Note that "TAg1" is an abbreviation. This phrase can only be used after it appears once.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 10-12 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (pages 1-93) provides adequate written descriptions for two full-length Tag 1 proteins (protein SEQ ID NOS: 3 and 18), isolated nucleic acid molecules consisting of the nucleotide sequence of SEQ ID Nos: 8 and 10 and a encoding protein of SEQ ID No: 8 which is consist of SEQ ID No: 9 and can serve as a tumor antigen. However, the specification fails to adequately describe: (1) a isolated cDNA comprising a nucleic acid sequence consisting of SEQ ID NO: 8 or 10 as recited in claims 1 and 2; (2) an isolated nucleic acid molecule encoding a protein comprising SEQ ID NO. 9 and its partial or fully complement as recited in claims 8-10;

and (3) an isolated nucleic acid molecule that encodes a protein having an amino acid sequence selected from the group consisting of SEQ ID NO: 9 and variants thereof that are at least 95% identical to SEQ ID NO: 9 wherein said variants exhibit Tag 1 activity as recited in claim 24-26. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, an isolated canine cDNA or mRNA in claims 1 and 2 was read as any kind of nucleic acid that is larger than a nucleic acid consisting of SEQ ID Nos: 8 or 10 and could be read as a chromosome having SEQ ID NO: 8 or 10 since claimed nucleic acid SEQ ID Nos. 8 and 10 only represent the forward and reverse strands of the 5' end of the disclosed full-length Tag1 and claimed partial cDNA do not include a disclosure of any open reading frame of which it would be a part of cDNA and would not be representative of the genus of cDNA because no information regarding the coding capacity of the cDNA molecule is disclosed. An isolated nucleic acid in (a) of claim 10, claims 11 and 12 was read as any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8 and could be read as a chromosome having SEQ ID NO: 8 since this nucleic acid molecule encodes a protein comprising the amino acid sequence SEQ ID NO: 9. An isolated nucleic acid in (b) of

claim 10, claims 11 and 12 was read as an isolated nucleic acid that is partially or fully complementary to any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8. An isolated nucleic acid of claims 24-26 was read as any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8 or its variants that are at least 95% identical to SEQ ID NO: 9 and exhibit Tag 1 activity, and could be read as a chromosome having SEQ ID NO: 8 or a chromosome having said variants of SEQ ID NO: 8 since this nucleic acid molecule comprising SEQ ID NO: 8 encodes a protein comprising the amino acid sequence SEQ ID NO: 9. Although the specification adequately describes two full-length Tag 1 proteins (protein SEQ ID NOS: 3 and 18), isolated nucleic acid molecules consisting of the nucleotide sequence of SEQ ID NOS: 8 and 10, and a encoding protein of SEQ ID NO: 8 which is consisted of SEQ ID NO. 9, claims 1-6, 10-12 and 24-26 encompass numerous unknown and unidentified nucleic acids that have polynucleotide sequences adding to 5', 3' and/or within of the nucleotide sequence of SEQ ID NO: 8 and partial or full complements of said unknown and unidentified nucleic acids or nucleic acids encoding various variants of SEQ ID NO. 8 that miss from the disclosure. It is unclear whether these variants of SEQ ID No: 8 in claims 1-6 10-12, and 24-26 (excluding variants with Tag 1 activity in claim 24) can be translated into an active Tag 1 which can still serve as a tumor antigen as SEQ ID No: 9 does. Note that an isolated nucleic acid molecule that encodes a protein having an amino acid sequence consisting of SEQ ID NO: 9 in claim 24 was read as any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8 and could be read as a chromosome having

SEQ ID NO: 8 since this nucleic acid molecule encodes a protein comprising the amino acid sequence SEQ ID NO: 9. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all the possible variant nucleic acid sequences which would be homologous or hybridize but do not correspond to nucleotide sequence consisting of SEQ ID NOS: 8 and 10 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.* Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polynucleotide consisting of SEQ ID No: 8 or 10 and a encoding protein of SEQ ID NO: 8 which is consisted of SEQ ID NO. 9 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Response to Arguments

In page 5, third paragraph bridging to page 8, first paragraph of applicant's remarks, applicant argued that: (1) "they disagree with the Examiner's statement that the specification fails to describe any nucleic acid molecule comprising a nucleic acid sequence SEQ ID No: 8 or 10 or any nucleic acid encoding SEQ ID No: 9." since "[T]he specification describes the isolation, sequencing and commercialization of cDNA's encoding two different full-length Tag1 protein (protein SEQ ID Nos. 3 and 18). Claimed nucleic acid SEQ ID Nos. 8 and 10 represent the forward and reverse strands of the 5' end of the disclosed full-length protein."; and (2) "[A]pplicants respectively argue that Claims 24-27 and the specification satisfy the requirements of 35 U.S. C 112, first paragraph" since "the guidance provided by Example No. 14 of the Synopsis of Application of Written Description Guidelines, which was prepared by the USPTO to train Examiners how to apply the requirements set out in Federal Register, Vol. 66, No. 4, pages 1099-1111." support applicant's position.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the examiner agreed with applicant that "[T]he specification describes the isolation, sequencing and commercialization of cDNA's encoding two different full-length Tag1 protein (protein SEQ ID Nos. 3 and 18). Claimed nucleic acid SEQ ID Nos. 8 and 10 represent the forward and reverse strands of the 5' end of the disclosed full-length protein." Although "[C]laimed nucleic acid SEQ ID Nos. 8 and 10 represent the forward and reverse strands of the 5' end of the disclosed full-length protein." as suggested by applicant, claimed partial cDNA(SEQ ID NO: 8 or 10) do not include a disclosure of any open reading frame of

which it would be a part of cDNA and would not be representative of the genus of cDNA because no information regarding the coding capacity of these cDNA molecules are disclosed. In view of open language in claims 1, 2, 10-12, and 24-26, an isolated canine cDNA or mRNA in claims 1 and 2 was read as any kind of nucleic acid that is larger than a nucleic acid consisting of SEQ ID Nos: 8 or 10 and could be read as a chromosome having SEQ ID NO: 8 or 10. An isolated nucleic acid in (a) of claim 10, claims 11 and 12 was read as any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8 and could be read as a chromosome having SEQ ID NO: 8 since this nucleic acid molecule encodes a protein comprising the amino acid sequence SEQ ID NO: 9. An isolated nucleic acid in (b) of claim 10, claims 11 and 12 was read as an isolated nucleic acid that is partially or fully complementary to any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8. An isolated nucleic acid of claims 24-26 was read as any kind o isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8 or its variants that are at least 95% identical to SEQ ID NO: 9 and exhibit Tag 1 activity, and could be read as a chromosome having SEQ ID NO: 8 or a chromosome having said variants of SEQ ID NO: since this nucleic acid molecule comprising SEQ ID NO: 8 encodes a protein comprising the amino acid sequence SEQ ID NO: 9. (see above rejection). There is no disclosure in the specification to teach any kind of isolated nucleic acid which had SEQ ID NO: 8 and was longer than the nucleotide sequence consisting of SEQ ID NO: 8 and any kind of isolated nucleic acid which had SEQ ID NO: 10 and was longer than the nucleotide sequence consisting of SEQ ID NO: 10 which are

claimed in this invention. Second, after carefully study the example No. 14 of the Synopsis of Application of Written Description Guidelines, the examiner notes that applicant appears to compare an Apple with an Orange since the claim in the example 14 is drawn to a protein while claims 24-26 are drawn to an isolated nucleic acid molecule which had different properties and functions. Therefore, the situation in the example No. 14 should not apply to claims 1-6, 10-12, and 24-26.

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the specification describes different washing temperatures for a hybridization assay (see specification, pages 17-21), the specification does not adequately describe specific washing temperature, 76 ^{0}C in claim 1. MPEP 2163.06 states that "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." In view of the embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of products encompass in the claims at the time of the application was filled. Therefore, the written description requirement has not been satisfied.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 2-5 are rejected as vague and indefinite because it is unclear that "the isolated nucleic acid" in claim 2 and "an isolated canine cDNA or mRNA" in claim 1 are the same molecule or not since "the isolated nucleic acid" is much broader than "cDNA or mRNA". Please clarify.

9. Claim 2 is rejected as vague and indefinite because it is unclear that "said nucleic acid" is "an isolated nucleic acid" in claim 2 or "a nucleic acid molecule consisting of a nucleic acid sequence selected from the group consisting of SEQ ID NO: 8 and SEQ ID No: 10" in claim 1. Please clarify.

10. Claim 11 is rejected as vague and indefinite because it is unclear that "said nucleic acid" in claim 11 is "an isolated nucleic acid" in claims 10 and 11 or " a nucleic acid molecule complementary to a nucleic acid molecule of (a)" in claim 10. Please clarify.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 5, 6, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanicola-Nadel *et al.,* (November 26, 1998).

Sanicola-Nadel *et al.,* disclose a SEQ ID NO: 85 (a cDNA clone of novel class of rat Kidney Injury-associated Molecules).

Regarding claim 1, since nucleotide sequences 255-407 in SEQ ID NO: 85 was 84.3% identical to whole sequence of SEQ ID NO: 8 (nucleotide sequences 1-144) of this instant application (see matching result), SEQ ID NO: 85 was considered as a cDNA molecule that hybridized with a nucleic acid molecule consisting of SEQ ID NO: 10 wherein SEQ ID NO: 10 was a full complementary strand of SEQ ID NO: 8 (see page 5 of applicant's remarks filed on August 6, 2002). Note that: (1) although Sanicola-Nadel *et al.,* did not disclose a cDNA made from canine, since there were no specific structural characteristics that distinguished cDNA taught

by Sanicola-Nadel *et al.*, from cDNA as recited in claim 1 and there was no indication of the divergence that would necessarily be present between rat and canine, there was no way to distinguish the prior art cDNA from that being claimed; and (2) although Sanicola-Nadel *et al.*, did not disclose a hybridization condition as recited in claim 1, since there were no specific structural characteristics that distinguished cDNA taught by Sanicola-Nadel *et al.*, from cDNA as recited in claim 1, cDNA taught by Sanicola-Nadel *et al.*, was considered to have an ability to hybridize with SEQ ID NO: 10. Furthermore, there was no evidence that cDNA taught by Sanicola-Nadel *et al.*, did not hybridize with SEQ ID NO: 10 in a conditions recited in claim 1.

Regarding claims 5 and 6, Sanicola-Nadel *et al.*, taught a cDNA of rat Kidney Injury-associated Molecule (KIM), a prokaryotic or eukaryotic host cell comprising an internalized vector having KIM-encoding nucleic acid insert, KIM fusion protein, physiological acceptable carrier, vehicle or excipient (see third paragraph in pages 3-6).

Regarding claim 10, since nucleotide sequences 359-379 in SEQ ID NO: 85 was 100% identical to nucleotide sequences 96-116 of SEQ ID NO: 8 of this instant application (see sequence matching), SEQ ID NO: 85 was considered as an isolated nucleic acid molecule complementary to a nucleic acid molecule of (a) as recited in (b) of claim 10.

Regarding claim 12, Sanicola-Nadel *et al.*, taught a cDNA of rat Kidney Injury-associated Molecule and physiological acceptable carrier, vehicle or excipient (see page 6, third paragraph).

Therefore, Sanicola-Nadel *et al.*, teach all limitations recited in claims 1, 5, 6, 10, and 12.

Response to Arguments

In page 9, second paragraph of applicant's remarks, applicant argued that:(1)"[A]pplicants have amended Claim 1 to recite hybridization and wash conditions which will result in about 90% stringency."; and (2) "the reference, which discloses a rat Kidney Injury-associated Molecule (KIM), neither teaches nor suggests nucleic acid molecules that are 90% identical to a canine tumor antigen of the present invention due to the vastly different sources and functions of the molecules in question.".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, there is no evidence that cDNA taught by Sanicola-Nadel *et al.*, did not hybridize with SEQ ID NO: 10 in a conditions recited in claim 1. Second, there is no evidence that hybridization and wash conditions recited in claim 1 result in about 90% stringency as applicant suggested. Third, although Sanicola-Nadel *et al.*, did not disclose a cDNA made from canine, since there were no specific structural characteristics that distinguished cDNA taught by Sanicola-Nadel *et al.*, from cDNA as recited in claim 1 and there was no indication of the divergence that would necessarily be present between rat and canine, there was no way to distinguish the prior art DNA from that being claimed.

13. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Sanicola-Nadel *et al.*, (November 26, 1998) as evidence by Stratagene Catalog (1994, page 296-299).

Sanicola-Nadel *et al.*, taught to clone KIM-encoding nucleic acid insert into a pBluescript plasmid vector (see page 26, last paragraph) wherein the cloning process was considered to be a

recombination process to produce a recombinant molecule as recited in claim 3. Since Stratagene Catalog (1994, page 296-299) disclosed maps of Bluescript SK +/- phagemid and Bluescript KS +/- phagemid wherein their multiple cloning site was flanked by T3 and T7 promoters (transcription control sequences as recited in claim 3), a pBluescript plasmid vector having KIM-encoding nucleic acid insert was considered as a recombinant molecule comprising an isolated nucleic acid molecule operatively linked to a transcription control sequence as recited in claim 3.

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanicola-Nadel *et al.*, as applied to, claims 1, 5, 6, 10, and 12 above, and further in view of Lathe *et al.,* (US Patent No.6,007,806, filed on December 12, 1997).

The teaching of Sanicola-Nadel *et al.,* have been summarized previously, *supra.*

Sanicola-Nadel *et al.*, do not disclose a recombinant virus as recited in claim 4.

Lathe *et al.,* do teach to make a recombinant virus having coding sequence (cDNA) of a tumor specific antigen (see columns 6 and 7).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a recombinant virus having a coding sequence of a protein as recited in claim 1 in view of the prior art of Sanicola-Nadel *et al.,* and Lathe *et al.*. One having ordinary skill in the art would have been motivated to modify cDNA taught by Sanicola-Nadel *et al.,* because a method for making a recombinant virus having a coding sequence of a protein was known in the art at the time the invention was made and it was known that the recombinant virus had a much higher transfection frequency than that of a regular transfection

using a pure nucleic acid, and the simple replacement of the coding sequence of one kind of protein (i.e., a tumor specific antigen taught by Lathe *et al.,*) from the coding sequence of another protein (ie.,KIM cDNA taught by Sanicola-Nadel *et al.*,) during the process of making a recombinant virus would have been, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because these products would be made by the same process.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page p, last paragraph bridging to page 10, second paragraph of applicant's remarks, applicant argued that "(1) "neither of the references, alone or in combination, teaches or suggests a nucleic acid molecule 90% identical to a nucleic acid molecule of the present invention.".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because the claims do not limit to a nucleic acid molecule 90% identical to a nucleic acid molecule consisting of SEQ ID NO: 8 or 10. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. No claim is allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
February 13, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600